REMARKS

By this amendment, claims 27, 30, 31, 33, 43, 44, 53, and 54 have been amended. Claims 34 and 39-62 stand withdrawn from consideration and thus claims 27-33 and 35-38 are currently under examination in the present application. For the reasons set forth below, Applicants submit that the present amendments and arguments place this application in condition for immediate allowance.

In the Office Action dated July 22, 2009, the Examiner provisionally rejected claims 27-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-28 of co-pending U.S. Application No. 11/815,736. In particular, the Examiner asserted that claims 25-28 of the co-pending application are directed to a composition comprised of 3-(4-chlorophenyl)propyl-3-piperodinopropyl ether (hydrochloride salt) and that claims 27-33 of the present application are drawn to the same invention. By the present amendments, claim 27 has been amended to include the proviso that when the compound (B) is a salt of 3-(4-chlorophenyl)propyl-3-piperodinopropyl ether (hydrochloride salt), the chlorhydrate salt of that compound is excluded. In this regard, co-pending Application No. 11/815,736 neither teaches nor suggests a composition that excludes the chlorhydrate salt of 3-(4-chlorophenyl)propyl-3-piperodinopropyl ether. Instead, co-pending Application No. 11/815,736, including claims 25-28 of that application, is only directed to a monochloride salt of 1-[3-[3-(4-chlorophenyl)propoxy] propyl]-piperidine. Accordingly, Applicants thus respectfully submit that the claims of the present application, as amended, are not obvious in view of

co-pending Application No. 11/815,736, and that the Examiner's obviousness-type double patenting rejection is respectfully traversed and should be withdrawn.

In the Office Action, the Examiner further rejected claims 30-33 and 38 under 35 U.S.C. §112, first paragraph as lacking enablement. In particular, the Examiner asserted that while the specification was enabling for compositions comprised of pharmaceutical salts, hydrates, hydrates salts, optical isomers, racemates and enantiomers of histamine H_3 antagonists, the specification did not reasonably provide enablement for compositions comprised of polymorphic crystalline structures of these compounds. Without addressing the merits of the Examiner's assertion, this rejection has been rendered moot by virtue of the present amendments. Specifically, by the present amendments, the phrase "polymorphic crystalline structures" has been removed from claims 30, 31, and 33. Similar amendments have also been made to withdrawn claims 43, 44, 53, and 54. Accordingly, Applicants submit that the Examiner's rejection, insofar as applied to the claims as amended, is respectfully traversed and should be withdrawn.

In the Office Action, the Examiner further rejected claims 27-33 and 35-38 under 35 U.S.C. §103(a) as being unpatentable over International Patent Application Publication No. WO 00/74784 ("Todd") and U.S. Patent No. 7,138,416 ("Schwartz"). In making the rejection, the Examiner asserted that, although Todd does not teach the co-administration of olanzapine with histamine H_3 receptor antagonists and/or inverse agonists, such as 3-(4-chlorophenyl)propyl-3-piperidinopropyl ether, it would have been obvious to formulate a composition comprised of olanzapine and 3-(4-chlorophenyl)propyl-3-piperidinopropyl ether because Schwartz teaches that 3-(4-

chlorophenyl)propyl-3-piperidinopropyl ether is effective in reducing weight gain and treating cognitive and attention deficits, and because Todd teaches that compositions comprised of olanzapine and H_2 histamine antagonists are effective in reducing weight gain. Furthermore, the Examiner also commented that even though Todd teaches a combination that includes H_2 antagonists instead of H_3 antagonists, one of ordinary skill in the art would have been motivated to substitute the H_2 antagonists with H_3 antagonists. For the reasons set forth below, Applicants submit that the Examiner's rejection is respectfully traversed and should be withdrawn.

The claims of the present application are directed toward pharmaceutical compositions that include an antipsychotic or antidepressant, which has the undesirable side effect of a gain in body weight or sedation, and an antagonist and/or inverse agonist of the histamine H_3 receptor, which suppresses or limits the undesirable side effect of weight gain, suppresses or limits the undesirable side effect on alertness, or increases the precognitive effect of the treatment. In contrast to the present application, Todd teaches that an H_2 receptor antagonist may be administered with antipsychotics to reduce the weight gain that may be caused by the antipsychotic. In this regard, and as the Examiner has acknowledged in the Office Action dated July 22, 2009, Todd includes no teaching or suggestion whatsoever that H_3 antagonists and/or inverse agonists can or should be co-administered with an antipsychotic. As such, to further support the obviousness rejections, the Examiner has asserted that Schwartz can be used to supply the missing teaching.

Schwartz describes that H_3 receptor antagonists may be used with psychiatric agents, such as neuroleptics, to increase the efficacy of those agents and to reduce their side effects. However, Schwartz does not specify what particular side effect may be reduced, and, more specifically, a reduction in weight gain is neither disclosed nor suggested by Schwartz. Indeed, the Examiner's comments on pages 8-9 of the Office Action that Schwartz teaches that "3-(4-chlorophenyl)propyl-3-piperidinopropyl ether...is effective in reducing weight gain" and that "H_3 inverse agonists and antagonists are effective in lessening weight gain associated with psychiatric drugs" could not be found in either Schwartz or Todd after a review of those references. Accordingly, it is thus the case that neither Todd nor Schwartz include any teaching or suggestion with regard to a pharmaceutical composition that includes an antipsychotic or an anti-depressant and an antagonist and/or inverse agonist of the histamine H_3 receptor, much less any teaching or suggestion that such a combination could be used to reduce the undesirable side effects associated with an antipsychotic or antidepressant.

Furthermore, it is also that case that one of ordinary skill in the art would not find it obvious to simply substitute H_2 antagonists with histamine H_3 antagonists and/or inverse agonists as the Examiner has suggested. As would be recognized by those of skill in the art, H_2 antagonists block the action of histamine in the stomach to thereby decrease gastric acid secretion. In contrast, H_3 antagonists act on H_3 receptors that are primarily found in the brain and cause the release of histamine (i.e., H_3 antagonists act in the same way as histamine). As such, upon a review of Todd, one of ordinary skill in the art would not have even contemplated that H_3 antagonists could be combined with an antipsychotic

drug to achieve a desired reduction in weight gain because Todd clearly teaches that H_2 agonists, which have a different mode of action, should be used to reduce weight gain. In this regard, one of ordinary skill in the art would also not have considered that the reduction in side effects referred to in Schwartz would include weight gain reduction, because Todd clearly teaches that H_2 antagonists are responsible for weight gain reduction. Accordingly, and in light of the teaching of Todd and Schwartz, it simply cannot be regarded as obvious to substitute an H_2 antagonist with an H_3 receptor antagonist as the Examiner has suggested.

In light of the foregoing discussion, Applicants thus submit that the present invention is not rendered obvious by the cited references and that the claims of the present application are clearly patentable over those references. Applicants thus submit that the Examiner's rejections on the basis of those references is respectfully traversed and should be withdrawn.

In light of the amendments and arguments provided herewith, Applicants submit that the present application overcomes all prior rejections and objections and has been placed in condition for allowance. Such action is respectfully requested.

Respectfully submitted,

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